70. (New) A method for inducing an immune response in a patient, comprising administering to the patient the composition of any one of claims 66-69.

REMARKS

Favorable reconsideration of the instant application in view of the present amendment and the following comments is respectfully requested. With the above amendment, claims 2, 12-15, 17-22, and 31 are canceled and new claims 61-70 are added. Applicants urge that no new matter is added by this amendment and that support for the new claims can be found throughout the specification as filed. In particular, support for 75% and 95% identity can be found, for example, on page 24, lines 1 – 10. Support for immunostimulants and adjuvants can be found, for example, on page 95, line 9 – page 96, line 28. Support for inducing an immune response and for Th1-type response can be found, for example, on page 95, lines 22 – 25. Support for stimulation of T cells can be found throughout the application as filed, in particular on page 81, line 25 – page 82, line 2. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1, 2, 12-15, 17-22 and 31 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In particular, the Examiner alleges that the phrase "moderately stringent conditions" in claim 1 is vague and not adequately defined in the specification. As noted above, claim 1 has been cancelled, without prejudice or acquiescence. Accordingly, this rejection is now moot.

Rejection under 35 U.S.C. § 101

The Examiner rejects claims 1-3, 12-15, 17-22 and 31 under 35 U.S.C. § 101 as lacking a credible or well-established utility. In particular, the Examiner alleges that because

there is no biological activity attributed to the polypeptide set forth in SEQ ID NO:176, and because there is an alleged lack of support for the association of said polypeptide with a particular disease such as cancer, that there is no specific and substantial utility to be ascribed to the claimed polypeptide.

Applicants respectfully traverse the grounds for this rejection.

Applicants submit that the presently claimed invention is amply supported by specific, substantial and credible utilities described in the specification as originally filed. The instant specification discloses, for example at page 122, line 19 – page 123, line 4, that SEQ ID NO: 175, encoding the polypeptide of SEQ ID NO: 176 (referred to as L523S), has a lung cancer-associated expression pattern. More particularly, L523S was found, by RT-PCR and Northern analyses, to be expressed in a majority of lung cancer samples tested, with no expression observed in normal lung. Furthermore, as described in the specification in Example 5 on page 130, lines 12 – 14, immunohistochemical analysis using polyclonal antibodies against L523S demonstrated staining in all lung cancer samples tested but not staining in normal lung, kidney, liver, colon, bone marrow or cerebellum. Therefore, the skilled artisan would readily appreciate in light of the instant disclosure, that, for example, antibodies generated against the claimed polypeptides would be useful in the detection of lung cancer. Applicants urge that the biological function of the L523S polypeptide set forth in SEQ ID NO:176 is irrelevant for this illustrative utility of the detection of lung cancer. Rather, it is the lung tumor-specific expression profile of this polypeptide described in the specification as filed, that provides a credible or well-established utility. Applicants submit that the above remarks are equally applicable to the newly added claims directed to immunogenic compositions comprising polypeptides comprising the sequence set forth in SEQ ID NO:176, sequences with 75-95% identity thereto, or portions thereof. In light of the above remarks, Applicants respectfully request reconsideration of the Examiner's rejection. Moreover, on the same grounds, applicants request reconsideration of the Examiner's related rejection under 35 U.S.C. 112, first paragraph, alleging that in the absence of utility, one skilled in the art would not know how to use the claimed invention.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner rejects claims 1-3, 12-15, 17-22 and 31 under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled. More specifically, the Examiner alleges that the claimed polypeptide comprising at least an immunogenic portion of SEQ ID NO:176 or a variant thereof, or a polypeptide comprising at least an immunogenic portion of an amino acid sequence encoded by a polynucleotide sequence that hybridizes to SEQ ID NO:175 under moderately stringent conditions would encompass numerous unknown and unidentified polypeptides that differ dramatically from SEQ ID NO:176. The Examiner further alleges that there is no indication of regions or specific amino acids within the polypeptide of SEQ ID NO:176 where mutations or variations would be tolerated with any change of the functional characteristic of said polypeptide and regions where they would not be tolerated. The Examiner alleges that it would require one skilled in the art at the time of the invention undue experimentation to practice the full scope of the invention claimed.

Applicants respectfully traverse this rejection on the following grounds.

Applicants note that claims 1-3, 12-15, 17-22 and 31 have been canceled from this application, without prejudice or acquiescence. The currently claimed invention is drawn to immunogenic compositions comprising an immunostimulant and a polypeptide selected from the group consisting of (i) a polypeptide comprising the amino acid sequence provided in SEQ ID NO:176, or a portion thereof; (ii) a polypeptide comprising an amino acid sequence having at least 75% identity to the sequence provided in SEQ ID NO:176, or a portion thereof; and (iii) a polypeptide comprising an amino acid sequence having at least 90% identity to the sequence provided in SEQ ID NO:176, or a portion thereof; wherein said polypeptide can be used for the detection of lung cancer, or wherein said polypeptide is capable of stimulating T cells that recognize the polypeptide set forth in SEQ ID NO:176. Applicants submit that this claimed subject matter is indeed fully enabled by the instant specification. In particular, support for 75% and 95% identity can be found, for example, on page 24, lines 1 – 10. Support for immunostimulants and adjuvants can be found, for example, on page 95, line 9 – page 96, line 28. Support for inducing an immune response and for Th1-type response can be found, for example, on page 95, lines 22 – 25. Support for stimulation of T cells can be found throughout the application as filed, in particular on page 81, line 25 – page 82, line 2.

With respect to the Examiner's allegation that variants of the claimed polypeptide would not have the same biological function as the recited sequences, Applicants submit that the limitations recited in the newly added claims are such that the polypeptide comprising a sequence selected from the group consisting of sequences having at least 75%-90% identity to SEQ ID NO:176, or portions thereof, **can be used for the detection of lung cancer** (claims 61-65) or **contain an amino acid sequence that is capable of stimulating T cells that recognize the polypeptide set forth in SEQ ID NO:176** (claims 66-70) (emphasis added). Applicants urge, as mentioned above in the context of the rejection under 35 U.S.C. § 101, that the biological function of the L523S polypeptide set forth in SEQ ID NO:176, or a polypeptide having at least 75%-90% identity thereto, is irrelevant to its use in either the detection of lung cancer or its ability to stimulate a T cell response. Rather, it is the lung tumor-specific expression profile of this polypeptide described in the specification as filed, that provides a credible or well-established utility. Applicants submit that one skilled in the art, using only routine methodologies described in the instant specification (*e.g.* Example 5) and/or available within the general level of knowledge in the art, and without undue experimentation, could readily determine whether the claimed polypeptide compositions could be used for the detection of lung cancer. For example, such a polypeptide could be used to generate antibodies and these antibodies could then be tested for their ability to detect L523S in lung cancer samples. Likewise, Applicants submit that one skilled in the art, using only routine methodologies described in the instant specification and/or available within the general level of knowledge in the art, and without undue experimentation, could readily determine whether the claimed polypeptides could stimulate T cells that are specific for the polypeptide of SEQ ID NO:176. Thus, Applicants urge that the pending claims fully satisfy the enablement requirements of 35 USC § 112, first paragraph, and that the rejection of the claims under 35 USC § 112, first paragraph, may be properly withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

The Examiner rejects claims 1-3, 12-15, 17-22 and 31 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification in a manner that would convince one of ordinary skill in the art at the time the instant application was filed

that the Applicants were in possession of the invention as claimed. In particular the Examiner alleges that the specification does not disclose common attributes or characteristics that identify members of the claimed genus, and because the genus is highly variant, the disclosure of SEQ ID NO:176 is insufficient to describe the genus.

Applicants respectfully traverse the rejection and submit the instant specification is clearly described in sufficient detail for one of ordinary skill in the art to reasonably conclude that the Applicants were in possession of the claimed polypeptide compositions at the time the instant application was filed. Applicants note that claims 1-3, 12-15, 17-22 and 31 have been canceled from this application, without prejudice or acquiescence. The currently claimed invention is thus drawn to immunogenic compositions comprising an immunostimulant and a polypeptide selected from the group consisting of (i) a polypeptide comprising the amino acid sequence provided in SEQ ID NO:176, or a portion thereof; (ii) a polypeptide comprising an amino acid sequence having at least 75% identity to the sequence provided in SEQ ID NO:176, or a portion thereof; and (iii) a polypeptide comprising an amino acid sequence having at least 90% identity to the sequence provided in SEQ ID NO:176, or a portion thereof; wherein said polypeptide is useful for the detection of lung cancer, or wherein said polypeptide is contains an amino acid sequence that is capable of stimulating T cells that recognize the polypeptide set forth in SEQ ID NO:176.

Applicants urge that the U.S.P.T.O. has indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an applicant discloses functional and/or descriptive information concerning the specie(s) in an application, *e.g.*, a distinguishing identifying characteristic common among the members of a claimed genus (see *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, para. 1, "Written Description" Requirement* - Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111). For example, at the bottom of pg. 1105, the *Guidelines* state that, "(a)n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." Applicants submit that the skilled artisan would readily understand, in light of the applicants' disclosure, the single identifying characteristic common to the claimed polynucleotides, i.e., the ability to be used in

the detection of lung cancer or alternatively the ability to stimulate T cells that recognize the polypeptide set forth in SEQ ID NO:176.

In light of the above remarks, Applicants respectfully submit that the skilled artisan, in view of this disclosure, would concur that applicants were in possession of the presently claimed compositions at the time the application was filed. Accordingly, Applicants request that this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over Mueller-Pillasch *et al.* (*Oncogene 14*:2729-2733, 1997). In particular, the Examiner asserts that Mueller-Pillasch *et al.* teach a polypeptide identical to SEQ ID NO:176.

Applicants note that claims 1-3 have been canceled without prejudice or acquiescence. Applicants further note that the newly added claims are directed to immunogenic compositions comprising an immunostimulant and a polypeptide selected from the group consisting of (i) a polypeptide comprising the amino acid sequence provided in SEQ ID NO:176, or a portion thereof; (ii) a polypeptide comprising an amino acid sequence having at least 75% identity to the sequence provided in SEQ ID NO:176, or a portion thereof; and (iii) a polypeptide comprising an amino acid sequence having at least 90% identity to the sequence provided in SEQ ID NO:176, or a portion thereof.

Applicants acknowledge that Mueller-Pillasch describes a polypeptide sequence of SEQ ID NO: 176. However, Mueller-Pillasch does not describe any association of that polypeptide sequence with lung cancer. Furthermore, Mueller-Pillasch does not teach or suggest combining the polypeptide of SEQ ID NO:176 with an adjuvant in an immunogenic composition, as described in the instant application and as currently claimed. Thus, Applicants urge that Mueller-Pillasch *et al.* does not anticipate the newly added claims. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current Amendment, the first page of which is captioned "Version with Markings to Show Changes Made."

Applicants respectfully submit that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If a teleconference would further advance the prosecution of this case, the Examiner is encouraged to telephone the undersigned at (206) 622-4900.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-3, 12-15, 17-22, and 31 have been canceled.

New claims 61-70 have been added.

In the Specification:

The paragraph on page 1, beginning on line 5, has been replaced with the following corrected paragraph.

The present application is related to U.S. Patent Application Nos. 09/662,786, filed September ~~26~~15, 2000; 09/643,597, filed August 21, 2000; 09/630,940 filed August 2, 2000; 09/606,421 filed June 28, 2000; 09/542,615 filed April 4, 2000; 09/510,376 filed February 22, 2000; 09/480,884 filed January 10, 2000; 09/476,496 filed December 30, 1999; 09/466,396 filed December 17, 1999; 09/285,479 filed April 2, 1999; 09/221,107 filed December 22, 1998; 09/123,912 filed July 27, 1998; 09/040,302 filed March 18, 1998; each a CIP of the previous application and each pending; and PCT Nos. US99/05798 filed March 17, 1999, published, and US00/08896 filed April 4, 2000, pending; all incorporated by reference herein.

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